NO. 10-17755

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RICHARD STENGEL; MARY LOU STENGEL,

Plaintiffs-Appellants/Petitioners,

vs.

MEDTRONIC INCORPORATED,
a Minnesota corporation,

Defendant-Appellee/Respondent.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA
HONORABLE RANER C. COLLINS, DISTRICT JUDGE
D.C. No. 4:10-CV-00318-RCC

APPELLANTS' PETITION FOR REHEARING EN BANC

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INTRODUCTION

In counsel's judgment, several compelling grounds for Rehearing *En Banc* exist including that the opinion of the panel (Dkt. 33-1) directly conflicts with an existing opinion by another court of appeals, and substantially affects an important issue in which there is an overriding need for uniformity within the meaning of Cir. R. 35-1.

FED. R. APP. P. 35(b) STATEMENT

The panel opinion directly conflicts with *Hughes v. Boston Scientific Corp*., 631 F.3d 726 (5th Cir. 2001). And also conflicts with *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). It involves an issue of exceptional and universal importance, *i.e.*, whether FDA pre-market approval renders a medical device manufacturer immune from state law tort liability for post-market failure to warn of a known danger in violation of both state law and its FDA reporting obligations?

The panel majority concluded that tort liability was preempted by virtue of federal regulation. Circuit Judge Noonan vigorously dissented, describing that majority opinion as "astonishing" in its scope and in light of Supreme Court precedent.

SUMMARY OF REASONS WHY THE PETITION SHOULD BE GRANTED.

1. Conflict among Circuits. The panel decision directly conflicts with an authoritative decision of the Fifth Circuit. The panel majority acknowledges the split among circuits: "We acknowledge that there is a division among the circuits whether state failure-to-warn claims are preempted by *Buckman*." *Op. at 4098*. The majority rejected the Fifth Circuit opinion in *Hughes* and also Justice Stevens' concurring opinion in *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) (joined by Justice Thomas), the only Supreme Court authority that directly addresses the specific preemption issue on appeal.

2. Conflict with Supreme Court Precedent. The panel decision conflicts with Supreme Court precedent. *Lohr* held that parallel state claims are not preempted where, as here, the defendant has violated Medical Device Act (MDA) regulations. As the panel's dissenter noted: "Not a word in *Buckman* limits *Lohr*." *Op. at 4105*. "*Lohr* is still binding law determined by the United States Supreme Court." *Id.*

Buckman did not involve the factual situation present here, *i.e.*, where the post-market failure to warn parallels the manufacturer's regulatory duty to report adverse events to the FDA. That specific issue was addressed in the *Buckman* concurring opinion that the panel majority rejected, not the *Buckman* majority opinion.

3. Exceptional Importance. As stated in Judge Noonan's dissent, the issue decided by the panel "is serious and the magnitude of its potential implications is great…" (*Op. at 4101*). "Are individuals injured by the malfunction of such [high-risk medical] devices without remedy against the manufacturers of them?" (*Id*). The panel majority's "conclusion, astonishing in its comprehensiveness, is equally astonishing in the light of binding federal law as determined by the United States Supreme Court" (*Id*) (referring to *Lohr*).

For each and all of the foregoing reasons *en banc* hearing is necessary to address the various conflicts, to secure clarity and uniformity of an exceptional and pervasive legal issue of national importance.

SUMMARY STATEMENT OF THE CASE

Medtronic obtained pre-market approval from the FDA to sell implantable pain pumps and catheters. The pumps and catheters were used to deliver pain medication directly into the space surrounding a patient's spinal cord. Post-market, Medtronic learned of the danger that in a significant number of patients the pump and catheter caused a granuloma to grow adjacent to the spinal cord. The granuloma could compress the spinal cord and cause permanent nerve injury and paralysis.

Medtronic was obliged to report these adverse events to the FDA under its regulations. But it violated its reporting obligations. The FDA conducted a routine

audit and discovered records of dozens of unreported adverse events. It issued a Warning Letter to Medtronic (reprinted in the Appendix to the panel's opinion), that caused Medtronic to disseminate urgent warning letters to physicians. Those supplemental warnings were later converted into a product recall by the FDA.

Richard Stengel had a Medtronic pain pump and catheter implanted. He suddenly lost strength and sensation in his legs. At the hospital, he came under the care of a neurosurgeon who was unaware that the pump and catheter could cause a granuloma. As a consequence, the tests that he ordered were not the kind that could detect a granuloma. Days later, Mr. Stengel was evaluated by a second neurosurgeon who had previously treated a granuloma patient. That neurosurgeon ordered a test that could detect a granuloma. By then, however, Mr. Stengel's paraplegia was permanent.

The Stengels filed a complaint against Medtronic in the Superior Court in Arizona alleging state law claims of negligence and products liability in accordance with Arizona's notice pleading standard. *Cullen v. Auto-Owners Ins. Co.*, 218 Ariz. 417, 419, 189 P.3d 344, 346 (2008) (rejecting the more rigorous federal standard adopted in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

Medtronic removed the case to federal district court and filed a Rule 12(b)(6) motion to dismiss before answer. Submitted with its motion was a request

to take judicial notice of FDA pre-market approval of Medtronic's pain pump. The Stengels opposed the motion and filed two motions. One for Rule 56(f) relief in order to engage in limited discovery to discover the facts of Medtronic's post-market failure to report and warn. And a second for leave to file an amended complaint to specifically allege that Medtronic was in violation of parallel Arizona and federal regulatory requirements concerning post-market failure to warn. Both of the Stengels' motions were denied. Medtronic's motion was granted and a judgment of dismissal was entered the same day.

The district court took notice of pre-market approval but did not indicate that it also took notice of the FDA Warning Letter and subsequent recall. In denying the Stengels' motions, it concluded that pre-market approval was dispositive of Medtronic's motion, and that no amendment or factual discovery could change that. The panel affirmed the district court's judgment dismissing the Stengels' case and denying their motions.

POINT I

EN BANC REVIEW IS NECESSARY TO RESOLVE CONFLICTING INTERPRETATIONS OF *BUCKMAN*.

The Supreme Court cases cited in the majority and dissenting opinions teach that claims based upon violations of state law duties are not preempted if those duties are parallel to the obligations imposed upon the manufacturer under the MDA. The same cases teach that state claims are impliedly preempted when they seek private enforcement of FDA regulations. The Supreme Court has not expressly decided whether state law claims are preempted if there is pre-market FDA approval but post-market the FDA determined that the manufacturer has violated FDA regulations parallel to state law. That is the case here.

The only specific Supreme Court guidance in point is Justice Stevens' concurrence in *Buckman* joined by Justice Thomas. That opinion concludes that such claims, as here, are not preempted because the plaintiff is able to establish causation "without second-guessing the FDA's decision making or overburdening its personnel…."

> If the FDA determines both that fraud has occurred and that such fraud requires the removal of a product from the market, state damages remedies would not encroach upon, but rather would supplement and facilitate, the federal enforcement scheme. *Cf. Medtronic, Inc. v. Lohr,* 518 U.S. 470, 495 (1996) (holding that the presence of a state-law damages remedy for violations of FDA requirements does not impose an additional requirement upon medical device manufacturers but "merely provides

> another reason for manufacturers to comply with . . . federal law").

531 U.S. at 354.

But the panel majority dismissed that reasoning on the ground that it did not achieve a majority vote. *Op. at 4097-98.* But the *Buckman* majority did not reject or consider that scenario. Unlike here, in *Buckman* the FDA regulators had not found violations by the device manufacturer. The claim there was based upon the theory that had the manufacturer provided additional information to the FDA, then pre-market approval would not have been granted. That is not the claim here.

The rationale for finding implied preemption in *Buckman* was that it was necessary to keep jurors in the 50 states from substituting their judgment in place of the federal regulators. Thus: "[F]raud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Agency, will later be judged insufficient in state court." *Buckman,* 531 U.S. at 351.

The situation here is manifestly different where regulators have acted post-market and pre-lawsuit and found that that the device manufacturer violated mandatory federal reporting obligations that parallel state law duties to warn. Dismissal of a parallel state law claim where the regulator has found a violation does not promote regulatory compliance. To the contrary, as Judge Noonan wrote,

any "pull" resulting from allowing the suit to go forward would be "for compliance with the MDA;" not substituting one's judgment for the FDA (*Op. at 4104*).

The dissent's analysis is straightforward. It points out that two Supreme Court opinions have held that state claims that parallel a device manufacturer's obligations under the MDA are not preempted (*Op. at 4103*). It distinguishes *Buckman* on the grounds that plaintiff's claims there existed solely by virtue of FDCA disclosure obligations and were not based upon state tort law (*Id. at 4104-05*). The Stengels' claims are based upon well-established common law duties to warn (*Id. at 4106*).

The panel majority's stated reason for finding implied preemption is that if Mr. and Mrs. Stengel's claim is allowed it could "exert an extraneous pull on the scheme established by Congress" (*Op. at 4098*). But the majority does not explain that conclusion or what it means in the context of this case. Nor can it logically follow where the FDA has already found regulatory violations by the device manufacturer that parallel state law failure to warn violations.

The *En Banc* panel should adopt Judge Noonan's analysis and interpretation of *Buckman*.

POINT II

EN BANC REVIEW IS NECESSARY TO DECIDE WHETHER THERE SHOULD BE UNIFORMITY WITH THE FIFTH CIRCUIT.

In *Hughes*, the Fifth Circuit overruled an implied preemption defense where, as here, evidence supported the conclusion that the FDA had determined that the manufacturer had violated its duty to timely report adverse events. The Court concluded that upholding an implied preemption defense under those circumstances would be inconsistent with the Supreme Court's opinion in *Riegel v. Medtronic*, 552 U.S. 3121 (2008), decided after *Buckman*:

> Boston Scientific's interpretation of *Buckman* barring this otherwise parallel state claim is inconsistent with the Supreme Court's reasoning in *Riegel*, decided long after *Buckman.*

631 F.3d at 775.

Hughes is in accord with the well-established presumption against preemption:

> Preemption analysis starts with the assumption that "the historic police powers of the States [a]re not to be superseded . . . unless that was the clear and manifest purpose of Congress."

Rice v. Santa Fe Elevator Corp., 331 U.S. 218 (1947).

The panel majority rejected *Hughes* because it misread *Buckman*. And, as the dissent noted, its conclusion is contrary to Supreme Court's decision in *Lohr*:

> Pellucidly, the Supreme Court has twice interpreted the MDA and held states may provide a damages remedy. In the language of *Lohr*, it would be "strange" if the Court expressly preserved state remedies from preemption but believed such remedies were implicitly rejected by the statute.

Op. at 4104.

Buckman predated *Riegel* and distinguished *Lohr*:

> Not a word in *Buckman* limits *Lohr*. The majority invoke it but do not show that it has application here. *Riegel* demonstrates that *Lohr* is still binding law determined by the United States Supreme Court.

Op. at 4105.

In *Lohr,* the Supreme Court held that parallel state claims could be brought where there had been a violation of MDA regulations. That is the case here, unlike *Buckman*:

> It is, to say the least, "difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct," *Silkwood v. Kerr-McGee Corp.,* 464 U.S. 238, 251 (1984), and it would take language much plainer than the text of § 360k to convince us that Congress intended that result.

518 U.S. at 487.

Neither *Buckman* nor *Medtronic, Inc., Sprint Fields Leads Prods. Liab. Litig.,* 623 F. 3d 1200 (8th Cir. 2010), relied upon by the panel majority, dealt with the case presented here. That was addressed in the *Buckman* concurring opinion:

> Under those circumstances, respondent's state-law fraud claim would not depend upon speculation as to the FDA's behavior in a counterfactual situation but would be grounded in the agency's explicit actions. In such a case, a plaintiff would be able to establish causation without second-guessing the FDA's decision making or overburdening its personnel, thereby alleviating the Government's central concerns regarding fraud-on-the-agency claims.

531 U.S. at 864-65, Stevens, J., joined by Thomas, J.

The panel majority does not refute that reasoning. *Hughes* was correctly decided and should also be the law in this Circuit.

POINT III

EN BANC REVIEW IS NECESSARY TO ADDRESS AN ISSUE OF EXCEPTIONAL IMPORTANCE.

Pre-market approved medical devices are pervasive and affect the health and lives of many patients. If a manufacturer discovers and ignores dangers revealed post-market, should it be immune from liability to those whom it injures or kills?

The panel majority converts the implied preemption of those state tort actions which seek to second-guess regulators into immunity from liability for all manufacturers where the regulators have acted pre-lawsuit in parallel with and in harmony with the asserted state tort law claim. That is a *non sequitur* with Draconian results. As the dissent notes, the result is sweeping in scope and effect, "astonishing in its comprehensiveness" given the extensive use of such devices and the holding that the MDA preempts "any state remedy of damages for a violation

of a state requirement paralleling the MDA" (*Op. at 4202*).

The FDA statute was enacted to promote public safety. Immunizing the manufacturer from all tort liability does not serve that interest. The Supreme Court in *Lohr* described that result as one of "perverse effect":

> Medtronic's construction of § 360k would therefore have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation in order "to provide for the safety and effectiveness of medical devices intended for human use," 90 Stat. 539 (preamble to Act).

518 U.S. at 487.

It is an exceptionally serious step to eliminate a legal remedy for a patient who has been rendered paraplegic by a defective medical device where post-market the manufacturer was informed but chose not to warn of the danger. Before that extreme result is final, more should be required than the panel majority's obscure "extraneous pull" rationale. The *En Banc* panel should follow *Lohr,* in accordance with Judge Noonan's analysis and rationale.

CONCLUSION

The Petition for *En Banc* Rehearing should be granted.

DATED this 27th day of April, 2012.

HARALSON, MILLER, PITT,
FELDMAN & McANALLY, P.L.C.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of FRAP 40-1(a) because it contains 2449 words according to Microsoft Word:mac 2011.

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DATED this 27th day of April, 2012.

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vs.

Medtronic Inc.,
Defendant and Appellee.

APPELLEE MEDTRONIC, INC.'S RESPONSE TO PETITION FOR REHEARING EN BANC

Appeal From The United States District Court for the
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I. INTRODUCTION

Plaintiffs argue that the panel's opinion is so off-base that it clears the steep threshold required for rehearing en banc. But there is no need for the Court to further invest its scarce resources in this case. Existing Supreme Court decisions already mark the boundaries of the express and implied preemption analysis relevant here and the panel's opinion faithfully follows the Supreme Court's guideposts. En banc review plainly would not change the Supreme Court's guidance or the preemption principles that controlled the result in this case. In particular:

- The panel's opinion upholding dismissal of the state tort law causes of action in the complaint does not create an intra-circuit conflict, nor does the petition suggest that that is the case;
- The panel's opinion upholding dismissal is based in part on principles of express preemption set forth in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). The opinion creates no conflict with the holding in *Riegel* and the petition does not contend otherwise;
- The panel's opinion upholding dismissal also is based in part on implied preemption principles set forth in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), and 21 U.S.C. § 337(a). The opinion creates no conflict with the holding in *Buckman* and the petition again does not contend otherwise; and
- The panel's opinion identifies a purported conflict with the implied preemption analysis set forth in the Fifth Circuit's opinion in *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011), but en banc review can do nothing to settle that purported conflict.

Finally, with respect to medical device preemption, it is apparent that *Riegel* and *Buckman* "'create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption.'" Op. at 4096 (quoting *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)). As the panel's opinion explains, the Plaintiffs' tort claims simply did not fit through that gap. From any perspective, therefore, the petition should be denied.

II.
STATEMENT OF THE CASE

In 1976, Congress enacted the Medical Device Amendments ("MDA"), Pub. L. No. 94-295, 90 Stat. 539 (codified as amended at 21 U.S.C. § 360c *et seq*.) to the Food Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 60k(a), which created a comprehensive regime of detailed federal oversight over medical devices. The MDA represents Congress's attempt to strike a delicate balance between regulation and innovation. It was intended to both ensure "the safety and effectiveness of medical device[s]," 90 Stat. 539, while simultaneously "encourag[ing] the[] research and development" of "sophisticated, critically important" devices. S. Rep. No. 94-33, at 2 (1975); *see also* H.R. Rep. No. 94-853, at 12 (1976).

To achieve these goals, while at the same time ensuring that innovations in device technology would not be "stifled by unnecessary restrictions," H.R. Rep. No. 94-853, at 12, Congress incorporated into the MDA an "express preemption" clause that provides that no state may impose "any requirement" relating to the safety or effectiveness of a medical device or any other matter

regulated by the MDA that "is different from, or in addition to, any requirement applicable . . . to the device" under federal law. 21 U.S.C. § 360k(a).

This case involves a "Class III" medical device, one that supports or sustains "human life" or "presents a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii). The most innovative Class III devices must receive FDA approval before they are brought to market ("Premarket Approval" or "PMA") and they "incur the FDA's strictest regulation." *Buckman*, 531 U.S. at 344.

The FDA closely scrutinizes applications for Premarket Approval, "'weigh[ing] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360c(a)(2)(C)). The Agency "spends an average of 1,200 hours reviewing each application." *Id*. If the Agency is not satisfied with the information provided, it can demand more. *Id*. (citing 21 U.S.C. § 360e(c)(1)(G)). The FDA also may refer the application to a panel of outside experts. *Id*. (citing 21 C.F.R. § 814.44(a)). If, as a result of this review, the FDA is unable to approve the new device in its proposed design, manufacturing methods, or labeling, it can require revisions prior to approval. *Id.* at 319 (citing 21 C.F.R. § 814.44(e)).

This comprehensive statutory scheme, and the pervasive federal regulatory oversight that carries it into effect, have supported the application of express and implied preemption principles to state tort causes of action, including in several watershed decisions from the United States Supreme Court. The panel opinion here captures those principles and the cases implementing them.

Although the petition hardly mentions it, the foundation for the panel's opinion rests with the Supreme Court's decision in *Riegel*. Under *Riegel*, state tort claims are preempted when they would impose any requirement that is "different from" or "in addition to" those imposed through the Premarket Approval process. 552 U.S. at 327-28 (citing 21 U.S.C. § 360k(a)). The panel explicitly held that Plaintiffs' claims were expressly preempted with one possible exception,[1] and the petition does not challenge that portion of the panel's ruling. The panel also recognized that to the extent that Plaintiffs' failure-to-warn claim seeks to enforce federal regulations governing the reporting of product complaints to the FDA, that claim is barred under a straightforward application of *Buckman*, and 21 U.S.C. § 337(a), which together prohibit private plaintiffs from usurping the FDA's exclusive authority to enforce its own regulatory scheme.

Plaintiffs, of course, disagree with this conclusion, and the panel dissent also objected to the limitations on liability resulting from preemption. But *Riegel* and *Buckman* already account for concerns about patient safety and limitations on tort liability. Those cases recognize that preemption is the deliberate product of the legislative scheme Congress enacted for the regulation of Premarket-Approved Class III medical devices. *See Riegel*, 552 U.S. at 318 (recognizing that patient needs may

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[1] The panel did not reach a firm conclusion about express preemption for one claim from Plaintiff's proposed amended complaint, a failure-to-warn theory premised on an alleged failure to report complaints to the FDA in violation of federal regulations. *See* Op. at 4092 ("portions of the claims in the Stengels' proposed amended complaint ***could be*** interpreted to survive express preemption") (emphasis added); *id.* at 4093 ("***To the extent***" this theory is "actionable under state law, the state obligations parallel the federal requirements and thus are not expressly preempted") (emphasis added); *see also* discussion *infra* at 8.

cause the FDA to "approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives"); *id.* at 325 (recognizing the federal regulation may better protect patients than tort liability because a jury "sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court."); *Buckman*, 531 U.S. at 348 (describing FDA's comprehensive powers to regulate medical devices and punish violating manufacturers). The panel's opinion merely followed these controlling decisions and respected the balance Congress struck.

En banc review requires far more than disagreement with a panel's considered decision. *See Hart v. Massanari*, 266 F.3d 1155, 1172 n.29 (9th Cir. 2001) ("We do not take cases en banc merely because of disagreement with a panel's decision. . . . We take cases en banc to answer questions of general importance likely to recur, or to resolve intracircuit conflicts, or to address issues of transcendent public significance—perhaps even to curb a 'runaway' panel—but not just to review a panel opinion for error, even in cases that particularly agitate judges.") (alterations and internal quotation marks omitted) (quoting *EEOC v. Ind. Bell Tel. Co.*, 256 F.3d 516 (7th Cir. 2001) (en banc) (Posner, J., concurring)); *see also United States v. Strickland*, 601 F.3d 963, 987 (9th Cir. 2010) (en banc) ("The purpose of an en banc proceeding is not simply to determine whether a result in a particular case is correct, nor is an en banc court convened simply to second guess a three-judge panel.") (Reinhardt, J., dissenting). Here, Plaintiffs cannot show that the panel's opinion ignored controlling authority from this Court or the Supreme Court and en banc review therefore is neither warranted nor needed.

III.
EN BANC REVIEW IS NOT WARRANTED OR NEEDED

A. There Is No Intracircuit Split

Neither the petition nor the dissent suggests that there is any conflict between the panel decision and any other decision of this Court.

B. The Panel Opinion Does Not Conflict With Opinions From This Court Or The U.S. Supreme Court

Unable to identify any conflict with a prior decision of this Court, the petition strains to conjure a conflict with the Supreme Court's decisions in *Lohr* and *Buckman*. But, on analysis, there is no conflict there either. By focusing exclusively on the panel's implied preemption analysis, the petition ignores that Plaintiffs' sole surviving claim, a failure-to-warn claim, fails as a matter of state law and is in any event expressly preempted. The critical controlling authority on the issue of express preemption is *Riegel* and when *Riegel* is considered, it becomes apparent why there is no conflict with *Lohr* or *Buckman*.

There Is No Conflict With The Supreme Court's Decision In *Riegel*. *Riegel* established a straightforward two-step procedure for determining if state-law claims are preempted by Section 360k(a). First, the court must determine whether "the Federal Government has established requirements applicable to" the particular medical device. *Riegel*, 552 U.S. at 321. Claims involving a device that has received Premarket Approval automatically satisfy this condition. *Id.* at 322 ("[p]remarket approval . . . imposes [federal] 'requirements'" as that term is used in § 360k(a)).

Second, the court then must determine whether the plaintiff's state-law claim would impose requirements "different from, or in addition to" those

established by the FDA. *Id.* at 321; *see also id.* at 316 (quoting § 360k(a) and noting requirements must relate to either "'safety and effectiveness'" or "any other matter included in a requirement applicable to the device under" the Medical Device Amendments to the FDCA). In that regard, state common-law tort claims automatically impose state-law requirements as required by this second condition, and are preempted if they impose duties that differ from, or add to, the duties mandated by federal law. *Id.* at 324-25 (holding that duties imposed through state common-law tort claims constitute state "requirements"); *see also id.* at 330 (strict-liability and negligence claims preempted).

Thus, *Riegel* stands unequivocally for the legal propositions adopted and followed by the panel here—that state common-law causes of action that impose requirements "different from" or "in addition to" those imposed by the FDA through the Premarket Approval of a device are expressly preempted by Section 360k(a). At the same time, as the panel here also acknowledged, *Riegel* followed *Lohr* in recognizing that because the MDA's express preemption clause preempts only state law that would impose requirements that are "different" from or in "addition" to federal requirements, the express preemption clause is no direct bar to state law claims that impose requirements that are "parallel" to federal law. *Riegel*, 552 U.S. at 330 ("§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements") (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)).

In this case, the panel, as well as the dissent, had no difficulty concluding that the Plaintiffs' initial complaint was "preempted under section 360k and *Riegel*" because it involved claims that "would have required the trier of fact, as

a matter of state tort law, to conclude that the device should have either been designed differently from what the FDA required through premarket approval, or labeled with warnings different from what the FDA required." Op. at 4092. They likewise had no difficulty concluding that the proposed amended complaint was expressly preempted to the extent it relied "on the theory that Medtronic should have sent a medical device correction notice to physicians, whether or not the FDA ordered it." *Id.*

Plaintiffs' petition now rests on a theory, drawn from their proposed amended complaint, that the panel assumed might not be expressly preempted—that Medtronic had a duty to discover and warn the FDA about complaints about the product after Premarket Approval. Pet. at 2-3. Without deciding whether a claim premised on that purported duty was actionable under Arizona law, the panel concluded that a state-law claim would "parallel the federal requirements" and therefore not be expressly preempted "***[t]o the extent*** Medtronic's alleged violations of FDA regulations are actionable under state law." Op. at 4093 (emphasis added).

In fact, it is extremely unlikely that Plaintiff's state-law claim would actually survive scrutiny if examined under express preemption principles. To start, Plaintiffs have not identified any duty under Arizona law that would require a medical device manufacturer to inform the FDA of certain events particularly defined by federal regulations. And the authority which exists suggests that there is no such requirement under Arizona law. *Cf. Placencia v. I-Flow Corp.*, 2011 WL 1361562, at *3-*4 (D. Ariz. 2011) (Arizona does authorize tort liability for a claim that the defendant promoted a medical device for an off-label use in violation of the FDCA). There thus is no reason to believe that Medtronic's alleged violations of FDA regulations are actionable under state law.

Moreover, to escape express preemption as a true "parallel" claim, a plaintiff's state-law cause of action must be "identical" to, *Lohr*, 518 U.S. at 495, or "genuinely equivalent" to, the federal requirement, *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2011) (quoting *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005)). Yet, Plaintiffs' failure-to-warn theory does not implicate any state law duty that is "genuinely equivalent," much less "identical," to the asserted federal law reporting requirement. Ultimately, Plaintiff's state-law failure-to-warn claim must rest on an alleged duty to have warned Plaintiffs of some purported risk of which they were not aware.[2] But a state-law duty to have warned ***the Plaintiffs*** is not identical to a federal duty to have reported adverse events to ***the FDA***. Regardless of the adverse events that a manufacturer reports to the FDA, the manufacturer may not change a device's label, and thus may not issue additional warnings to consumers, without first receiving FDA approval. *See Riegel*, 552 U.S. at 319 ("the MDA forbids the manufacturer to make, without FDA permission, changes in . . . labeling" and if the manufacturer "wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application") (citing 21 U.S.C. § 360e(d)(6); 21 C.F.R. § 814.39(c)).

Finally, at bottom, Plaintiffs' failure-to-warn claim rests on the assertion that Medtronic had a state-law duty to provide warnings beyond those that had been authorized by the FDA through the PMA process. It is, however, clear

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[2] Arizona's common law imposes a duty on manufactures to warn ***consumers*** if the manufacturer knows or has reason to know that its product is likely to be dangerous. *See Anguiano v. DuPont*, 44 F.3d 806, 811-12 (9th Cir. 1995).

that any claim that a manufacturer "was required to give additional warnings" imposes "precisely the type of state requirement that is 'different from or in addition to' the federal requirement and therefore preempted." *In re Sprint Fidelis*, 623 F.3d at 1205 (citation and internal quotation marks omitted); *see also Riegel*, 552 U.S. at 329 (§ 360k(a) "[s]urely . . . would pre-empt a jury determination that the FDA-approved labeling for a [device] violated a state common-law requirement for additional warnings.").

In short, the only claim raised in the petition, Plaintiffs' failure-to-warn theory, is subject to dismissal under well-established express preemption principles from *Riegel* and *Lohr*. Given the dispositive effect of these express preemption principles, there is no reason to consider implied preemption, nor to grant rehearing en banc.

There Is No Conflict With The Supreme Court's Decision In *Buckman*. Plaintiffs do not claim that the panel decision conflicts with the Supreme Court's holding in *Buckman*. On Plaintiffs' account, "*Buckman* did not involve the factual situation present here." Pet. at 2. Thus, Plaintiffs' complaint is not that the panel disregarded *Buckman*, but instead that the panel did not follow the *Buckman* concurrence "on the ground that it did not achieve a majority vote." *Id.* at 7. Needless to say, the panel's failure to adhere to a concurring opinion that (by definition) did not achieve a majority among the Justices is no basis for rehearing en banc. In any event, the panel opinion represents a straightforward application of

Buckman's implied preemption principles, and does not warrant en banc review for that reason either.[3]

In *Buckman*, the Supreme Court addressed the issue of whether, and to what extent, "fraud-on-the-FDA" claims are impliedly preempted by the MDA. In that case, plaintiffs had attempted to bring state tort claims against the defendant for allegedly helping a manufacturer of bone screws obtain, from the FDA, approval for "off-label" uses of its product through section 510(k)'s "substantially equivalent" process. *Buckman*, 531 U.S. at 346-47. Plaintiffs alleged that the defendant had made false representations to the FDA in the manufacturer's section 510(k) application, that this led the FDA to clear the device for marketing when it should not have, and thus ultimately led to plaintiffs' injury. *Id.* The Supreme Court rejected plaintiffs' claims, concluding that because they existed solely by virtue of the MDA's disclosure requirement, they infringed upon the FDA's exclusive authority to police violations and were impliedly preempted by the MDA. *Id.* at 353-54.

The Court first noted that defendant's "dealings with the FDA were prompted by the MDA, and the very subject matter of [defendant's] statements were dictated by that statute's provision." *Id.* at 347-48. Acknowledging that "the relationship between a federal agency and the entity it regulates is inherently federal

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[3] The petition quotes the dissent's statement that "[n]ot a word in *Buckman* limits *Lohr*." Pet. at 2 (quoting Dissenting Op. at 4105). That may be true, but tacitly conflates express and implied preemption. *Lohr* addressed express preemption; *Buckman* addressed implied preemption. As the Supreme Court has repeatedly held, the inapplicability of an express preemption provision does not preclude the application of implied preemption principles. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000); *Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995).

in character because the relationship originates from, is govern by, and terminates according to federal," the Court then concluded that plaintiffs' claims were impliedly preempted because they conflicted with the regulatory scheme implemented by the MDA. *Id.* It reasoned that "[t]he conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objects." *Id.*

In reaching these conclusions, the Supreme Court noted its profound concerns that permitting state tort claims to proceed when they were based upon a duty that existed *solely* by virtue of the federal statutory scheme would upset that regulatory balance. It then advanced a number of reasons why that was so, including: (1) the risk that permitting plaintiffs' claims to proceed might deter manufacturers from pursuing off-label uses of their products for fear that they will be exposed to civil liability; and (2) the risk that permitting plaintiffs' claims to proceed would be cause applicants to fear that the adequacy of their disclosures to the FDA would be second guessed by state juries, even when they had been deemed adequate by the FDA, thereby causing applicants to submit voluminous, unnecessary information placing an additional burden on the FDA. *Id.* at 350-51. The Court called these concerns risks that the state tort claims would exercise an "extraneous pull" on the regulatory scheme. *Id.* at 353. Because plaintiffs' fraud-on-the-FDA claims existed *solely* by virtue of the defendant's disclosure obligations under the MDA, the Court found that the claims were preempted. *Id.* at 352-53.

As the panel opinion here carefully articulates, the same profound concerns that animated the application of implied preemption in *Buckman* support the application of implied preemption in this case. First, as in *Buckman*, the duty that

Plaintiffs claim Medtronic violated was a duty "[u]nder ***federal law and regulation***"—a duty to report certain events to the FDA. Op. at 4093 (quoting Sub. Am. Cmplt. ¶ 13) (emphasis added). The petition and dissenting opinion incorrectly assume that Arizona's common law duty to warn ***consumers*** is equivalent to a manufacturer's duty under the MDA to inform the *FDA* of "reportable corrections." This is not so. Neither has provided any authority for the assertion that Arizona's common law imposes a duty upon manufacturers to inform the federal government of possible defects in their products. Any such duty exists ***solely*** by virtue of federal law. This is precisely what *Buckman* was concerned with and why Plaintiffs' claims would infringe upon the federal regulatory scheme.[4]

Second, as in *Buckman*, allowing Plaintiffs to pursue claims that allege that Medtronic breached a duty that exists solely by virtue of federal regulation risks upsetting the delicate balance that the FDCA and its implementing regulations strike. Congress has specified that all actions to enforce the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a). Although "citizens may report wrongdoing and petition the agency to take action," *Buckman*, 531 U.S. at 349 (citing 21 C.F.R. § 10.30), there is no private right of action under the FDCA, *id.* at 349 n.4. Consistent with the agency's exclusive power to enforce the FDCA, the FDA has the authority to investigate violations of the Act, and to pursue a wide range of sanctions for violations of the Act, including "injunctive relief, 21 U.S.C. 332,

[4] Even if Plaintiffs could identify a state law duty to report adverse events to the FDA (*but see supra* 9-10), that would not save their claim from implied preemption. As the panel decision correctly notes, the *Buckman* Court held that the plaintiff's claims there were impliedly preempted notwithstanding the fact that the plaintiff was "seeking damages 'under state tort law.'" Op. at 4098.

civil money penalties, 21 U.S.C. 333(f)(1)(A), seizure of the device, 21 U.S.C. 334(a)(2)(D), and criminal prosecution, 21 U.S.C. 333(a), 18 U.S.C. 1001 (1994 & Supp. IV 1998)." Brief for United States as Amicus Curiae, *Buckman*, 531 U.S. 341 (2001) (No. 98-1768), 2000 WL 1364441, at *22. Permitting Plaintiffs' state-law tort action to proceed would not only be contrary to the plain language of 21 U.S.C. § 337(a), but would interfere with the FDA's ability to exercise its enforcement discretion "to achieve a somewhat delicate balance of statutory objects." *Buckman*, 531 U.S. at 348. Thus, the panel correctly concluded that dismissal was required by *Buckman*.

Plaintiffs (and the dissent) attempt to distinguish *Buckman* on the ground that in this case the FDA has already "found" that Medtronic violated the MDA by failing to inform the FDA of a "reportable correction." But that distinction is immaterial. While the absence of a prior FDA finding would surely make the Plaintiffs' attempt to directly enforce FDA regulations even more egregious, nothing in the categorical language of 21 U.S.C. § 337(a) suggests that actions to enforce the FDCA "shall be by and in the name of the United States" ***except*** when the FDA has previously found a regulatory violation. As noted above, Congress has vested the FDA with exclusive, discretionary enforcement authority which the agency exercises to achieve a "delicate balance of statutory objects." *Buckman*, 531 U.S. at 348. Here, the FDA determined that the appropriate enforcement action was to send Medtronic a letter identifying Medtronic's alleged failings. Allowing private plaintiffs to step in and bring a state-law tort action would interfere with, and is therefore impliedly preempted by, the statutory scheme adopted by Congress.

C. The Intercircuit Conflict Described In The Panel Opinion Does Not Justify En Banc Review

Plaintiffs also argue that en banc review is necessary to decide whether the Ninth Circuit should align itself with the Fifth Circuit's decision in *Hughes* instead of the Eighth Circuit's decision in *Bryant*. Pet. at 9-10. But the panel's decision to follow *Bryant* rather than *Hughes* is not only correct but provides no justification for en banc review. While the panel observed "there is a division among the circuits whether state failure-to-warn claims are preempted by *Buckman*," Op. at 4098, en banc review in this case could not eliminate the purported conflict because, regardless of outcome, there would still remain a perceived split between the Fifth and Eighth Circuits. Future courts already have the benefit of the insights provided in the majority and dissenting opinions here, and the substantial burden of en banc review would not add meaningfully to the analysis of the issues.

IV. CONCLUSION

The grounds supporting rehearing en banc are not present and the petition for rehearing en banc should be denied.

DATED: May 22, 2012

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CERTIFICATE OF COMPLIANCE
PURSUANT TO FED. R. APP. P. 32(c)(2) AND
NINTH CIRCUIT RULES 35-4 AND 40-1(a)

I, Michael K. Brown, certify that pursuant to Federal Rule of Appellate Procedure 32(c)(2) and Ninth Circuit Rules 35-4 and 40-1(a), the attached Response to Petition for Rehearing En Banc is double-spaced and was printed in proportionately spaced, fourteen-point CG Times type. It contains 4,192 words (petitions and answers must not exceed 4,200 words). In preparing this Certificate, I relied on the word count generated by Microsoft Word 2003.

DATED: May 22, 2012

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CERTIFICATE OF SERVICE

Richard Stengel, et al. v. Medtronic, Inc.
Ninth Circuit No. 10-17755

I, Michael K. Brown, declare:

I am employed in the County of Los Angeles, State of California. My business address is Reed Smith LLP, 355 South Grand Avenue, Suite 2900, Los Angeles, California 90071. I am over the age of eighteen years and not a party to the action in which this service is made.

I hereby certify that on May 22, 2012, I electronically filed the foregoing:

APPELLEE MEDTRONIC, INC.'S RESPONSE TO
PETITION FOR REHEARING EN BANC

with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system. All participants in the case are registered CM/ECF users will be served by the appellate CM/ECF system.

I declare under penalty of perjury under the laws of the United States of America that the above is true and correct. Executed on May 22, 2012, at Los Angeles, California.

S/-Michael K. Brown
Michael K. Brown